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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,792	09/23/2003	Bernard E. Cabana	50150/064001	4322

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

NOTIFICATION DATE	DELIVERY MODE
09/17/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/668,792	CABANA ET AL	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29 and 40-51* is/are pending in the application.

4a) Of the above claim(s) *6-29 and 40-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 49-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicants' Amendment filed June 25, 2007 is acknowledged. Claims 6-29 and 40-48 remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as drawn to non-elected inventions. Claims 1-5 and 49-51 remain under consideration.

In the last Office Action claims 1-5 and 49-51 remained provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of various co-pending applications. The conflicting claims are not identical, but they are not patentably distinct from each other because the claims of the co-pending applications recite pharmaceutical compositions or formulations comprising rifalazil.

Applicants again choose to hold these issues in abeyance. The provisional obviousness-type double patenting rejections of record of claims 1-5 and 49-51 are maintained over claims 43-45 of copending Application No. 10/948608; over claim 4 of copending Application No. 11/020870; and over claim 4 of copending Application No. 11/008597.

Claims 1-3 and 5 were rejected under 35 U.S.C. 102(a) as being anticipated by Rose et al., U.S. Patent 6,316,433, in the last Office Action. It was asserted Rose teaches pharmaceutical compositions comprising a unit dosage form of rifalazil in an amount at least of 1 mg or 5 mg for oral administration. See column 11, lines 38-53, Drug Formulation, lines 64, column 32, to column 33, line 4, as well as claims 11 and 16 in column 34.

Applicants argue each of the claims require the amount of rifalazil contained in the claimed unit dosage form falls between an upper and a lower limit and does not

encompass the recited limits themselves. Further, Applicants urge Rose does not teach a unit dosage form or an actual dose of 0.1 mg or 5 mg.

A unit dosage is a finite, discrete drug entity having a specific amount of that drug. Such packaging is presently entirely conventional. Rose teaches a dose of rifalazil from 1 mg to 50 mg orally. Accordingly, Rose teaches a finite, discrete drug entity, i.e., a drug unit, having 1 mg of rifalazil. See claim 11, column 34. The dose may optionally be administered orally in the form of a tablet or capsule. See claim 16, column 34. A clear disclosure of a 1 mg single dose is noted.

Applicants' argument is not persuasive. The rejection of record of claims 1-3 and 5 under 35 U.S.C. 102(a) as being anticipated by Rose et al., U.S. Patent 6,316,433, is maintained.

In the last Office Action claims 1-3, 5 and 49-51 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al., U.S. Patent 6,316,433, in view of Remington's Pharmaceutical Sciences. It was asserted Rose teaches pharmaceutical compositions comprising a unit dosage form of rifalazil in an amount at least of 1 mg or 5 mg for oral administration. See column 11, lines 38-53, Drug Formulation, lines 64, column 32, to column 33, line 4, as well as claims 11 and 16 in column 34. Remington provides motivation to prepare a pharmaceutical formulation for oral administration comprising an antibiotic having first and second dosage units with a higher amount of active antibiotic in the first dosage unit, as required by instant claim 50. Loading doses are used in many drug regimens when an urgent need exists to achieve a drug steady state. All pharmaceutical preparations that are dispensed to a patient are packaged in

pharmaceutical containers along with instructions for administration. The mere placement of instructions within a formulation comprising rifalazil would have been within the general knowledge of one of ordinary skill in the art at the time of the invention. Such a person would have been motivated to do so to promote proper use of the formulation to patients in need thereof and to facilitate patient compliance with a prescribed regimen. Providing such a formulation in a portable container, or in unit dose packaging, that can be transported to allow for convenient dosing, is conventional. It has been held that Applicant is not entitled to patent a known product by simply attaching a set of instructions to that product. See *In re Ngai*, 367 F.3d 1336,70 U.S.P.Q.2d 1862 (Fed. Cir. 2004). The determination of an optimal dosing regimen is well within the purview of those skilled in the art through no more than routine experimentation. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II).

In addition to arguments set forth *supra*, Applicants urge Remington provides a generic description of a loading dose regimen.

Applicants' argument is not persuasive. A unit dosage is a finite, discrete drug entity having a specific amount of that drug. Such packaging is presently entirely conventional. Rose teaches a dose of rifalazil from 1 mg to 50 mg orally. Accordingly, Rose teaches a finite, discrete drug entity, i.e., a drug unit, having 1 mg of rifalazil. See claim 11, column 34. The dose may optionally be administered orally in the form of a tablet or capsule. See claim 16, column 34. A clear disclosure of a 1 mg single dose is noted.

Remington is applied as a secondary reference to show a dosing regimen wherein a higher amount of active antibiotic is dispensed in a first dosage to achieve a therapeutic drug concentration quickly. Such loading doses, as taught by Remington, reflects conventional practice in that the first dose has a higher amount of drug and is followed by a second lower dose, considered to be a maintenance dose.

A reasonable interpretation of a claim reciting " an amount between 0.1 and 5 mg" would include a dose of 0.1 mg, as well as a dose of 5 mg.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

September 9, 2007

Phyllis Spivack.

1614

PHYLLIS SPIVACK
PRIMARY EXAMINER